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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,831	01/24/2001	David Houze	NOPH/100/JGK	7241

7590 05/02/2003

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	19

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental Office Action Summary	Application No. 09/768,831	Applicant(s) Houze et al.
	Examiner Isis Ghali	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 7, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-30* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment B, both filed 09/23/2002; and prior art, filed 01/07/2003.

The prior art has been considered as far as the translated portion of the reference. The references are listed on PTO-892 form.

Priority

1. This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/479,966, filed 01/10/2000." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "substantially only" is not clearly defining the composition regarding whether or not any other ingredients are present.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6-12, 26, 27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,994,267 ('267).

US '267 disclosed a dermal composition comprising (1) a drug, (2) a multipolymer that include (I) a mixture of polymers such as ethylene/vinyl acetate with a different polymer such as acrylic acid and (ii) a polyacrylate (abstract; col.2, lines 11-26; col.3, lines 60-65). The polyacrylate constitutes from 5-95% of the multipolymer and contains alkyl acrylate (containing carboxyl functional group), and has functional monomer such as hydroxy ethyl acrylate (col.4, lines 20-35). The acrylate polymer contains from 0-20% of a functional monomers (col.4, lines 20-24). The reference disclosed that the dermal composition permits an unusually low loading of medication

as well as high loading of medication into the dermal composition while maintaining the desirable physical properties and release rate (col.2, lines 5-10; col.3, lines 14-16). Examples 8 and 9 show composition comprising mixture of two acrylic polymers: Duro-Tak 80-1194 and Duro-Tak 80-1054. In example 8, the first acrylic polymer forms 2% and the second forms 38% of the total composition and that means the first acrylic polymer forms 5% of the total mixture of the first and second polymers; and example 9 the first polymer forms 32% and the second 2% of the total composition, and this means the first polymer forms 94% of the total mixture of the first and second polymers. Different polymers will inherently have different solubility and functionality, and one should be higher than the other. The reference disclosed a method for preparing the dermal composition comprising mixing the multipolymers and the drug in an appropriate liquid, casting the mixture and removing the liquid by evaporation (col.3, lines 49-58). The limitations of claims 1-4, 6-11 are met by US '267.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5, 13-25, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,994,267 ('267) in view of US 5,474,783 ('783).

US '267 teaches a dermal composition comprising (1) a drug, (2) a multipolymer that include (I) a mixture of polymers such as ethylene/vinyl acetate with a different polymer such as acrylic acid and (ii) a polyacrylate (abstract; col.2, lines 11-26; col.3, lines 60-65). The polyacrylate constitutes from 5-95% of the multipolymer and contains alkyl acrylate (containing carboxyl functional group), and has functional monomer such as hydroxy ethyl acrylate (col.4, lines 20-35). The acrylate polymer contains from 0-20% of a functional monomers (col.4, lines 20-24). The reference disclosed that the dermal composition permits an unusually low loading of medication as well as high loading of medication into the dermal composition while maintaining the desirable physical properties and release rate (col.2, lines 5-10; col.3, lines 14-16). Examples 8 and 9

show composition comprising mixture of two acrylic polymers: Duro-Tak 80-1194 and Duro-Tak 80-1054. In example 8, the first acrylic polymer forms 2% and the second forms 38% of the total composition and that means the first acrylic polymer forms 5% of the total mixture of the first and second polymers; and example 9 the first polymer forms 32% and the second 2% of the total composition, and this means the first polymer forms 94% of the total mixture of the first and second polymers. Different polymers will inherently have different solubility and functionality, and one should be higher than the other. The reference disclosed a method for preparing the dermal composition comprising mixing the multipolymers and the drug in an appropriate liquid, casting the mixture and removing the liquid by evaporation (col.3, lines 49-58).

US '267 does not teach the amount as claimed in claim 5; the particular drugs including haloperidol, nicotine, clonidine and scopolamine; and the backing and the release liner.

US '783 teaches a transdermal drug delivery system wherein the a blend of at least two polymers having two different solubility parameters adjusts the solubility of a drug in the polymeric blend and thereby modulate the delivery of the drug from the system and through the dermis. The reference discloses a pressure sensitive adhesive composition which is suitable as a matrix for controlled release of a bioactive agent therefrom comprising a blend of a first polymeric adhesive material having a first solubility parameter and a second polymeric adhesive material having a second

solubility parameter, the first and second solubility parameters being different from one another (abstract; col.3, lines 36-60; col.6, lines 13-19). The blend therefore has a characteristic net solubility parameter which can be preselected to adjust the saturation concentration of the bioactive agent in the composition and thereby control its release either upward or downward depending upon whether the rate of release is to be enhanced or retarded (col.4, lines 40-45). The transdermal permeation rate is also controlled by varying the relative proportions of the polymers comprising the multiple polymer adhesive system (col.8, lines 3-5). The blend comprising an acrylic based polymer in an amount of 2-96 % (col.4, lines 15-16; col.9, lines 22-26, 51-54). Drugs used in the composition include haloperidol (col.4, line 1; col.11, line 4), nicotine (col.11, line 8), clonidine (col.10, line 54) and scopolamine (col.11, line 38). Functional monomers used by the reference are acrylic acid, DURO-TAK and hydroxy ethyl acetate (col.9, lines 21-54; col.15, lines 50-55). The reference teaches a method of preparation of the transdermal delivery device includes the steps of mixing the ingredients, coating the formulation onto protective release liner drying solvents in the oven and applying a backing material and release liner (col.15, lines 20-35; col.4, lines 34, 35).

It is within the skill in the art to select optimal parameters such as ratios and weight percents in order to achieve a beneficial effect, thus the claimed amounts of claim 5 not considered critical, absent evidence of superior and unexpected results.

Thus, it would have been obvious for one having ordinary skill in the art at the time the invention was made to provide a dermal composition comprising a blend of two polymers and select the amount of the first and second polymer according to the desired property (see '267, col.4, lines 59-62), and to provide a transdermal system comprising drug matrix, backing and release liner (as disclosed by US '783), and also select the drug that is known to be delivered transdermally motivated by the teaching of US '783 (in col.3, line 61-col.4, line 2) that antipsychotic (include haloperidol and nicotine), cholinergic agent (include scopolamine), and cardioactive agents (include clonidine) are preferred for delivery in a composition having blend of polymers having different solubility parameters to modulate the delivery of the drugs through the dermis, with reasonable expectation of success to control the rate of drug delivery.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday-Friday from 7:00 to 5:30 Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali

Patent Examiner

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600